

REMARKS

Claims 1-11 and 15-24 are pending in the case, with claims 1 and 15 being amended hereby. All of the pending claims stand rejected over either Luther U.S. Patent No. 4,964,854 ("Luther") or the combination of Jagger et al U.S. Patent No. 4,781,692 and Chang et al U.S. Patent No. 5,419,766 ("Jagger" and "Chang", respectively). In that regard, (a) claims 1-7, 9 and 15-23 stand rejected as anticipated over Luther, with remaining, dependent claims 8, 10, 11 and 24 being rejected for obviousness over Luther, and (b) all of the claims stand rejected for obviousness over the combination of Jagger in view of Chang. As set out below, it is submitted that these rejections should be withdrawn.¹

Luther U.S. Patent No. 4,964,854

Claims 1-7, 9 and 15-23 are rejected as allegedly anticipated by Luther, with the remaining claims, dependent claims 8, 10, 11, and 24, being rejected as allegedly obvious thereover. As will be explained below, Luther entirely lacks one of the claimed elements and so can neither anticipate nor render obvious the claimed invention. In particular, all of the pending claims specify a gasket defining an opening through which the needle shaft is movable, with that opening being nominally almost identical in size to the circumference of the needle shaft. Support therefore is set out on page 5, lines 19 and 20 of the application as filed. Despite the assertion in the Official Action that the spring ferrule 60 of Luther is a gasket, with all due respect such a structure is not at all a gasket, and certainly not one with the nominally-sized opening as claimed herein.

¹ In order to streamline prosecution, the present Response focuses on certain distinctions which are submitted to be sufficient to overcome the rejections. Applicant does not waive any other argument available for patentability of any of the claims over the cited references or any other art, and reserves the right to present such arguments should that prove necessary.

The term "gasket" is well understood as a structure with a closed-perimeter opening and through which another member can pass. Here, that other member is the shaft of the needle cannula, with the opening almost identical in size to the circumference of the needle cannula shaft.

By contrast, the Official Action cites to spring ferrule 60 of Luther and, in particular, to the annular ring 62 at the back end of the ferrule 60 as if it were a gasket in view of the alleged sealing between ring 62 and body 42. But the focus here is on the relationship between the needle cannula shaft and the opening of the gasket. As can be readily seen in Luther, the opening defined by annular ring 62 is substantially larger than the shaft circumference. Hence, it can in no way be considered to be a gasket as claimed, as it is not at all closely sized to the shaft circumference.

At the other end of the spring ferrule 60 are spring leaflets 64, but they are nominally sized to be less than the circumference of the shaft, as they are intended to spring radially inwardly into a recessed area of the shaft so as to fit behind annular shoulder 29 to limit movement of the needle cannula. That shoulder is at the circumference of the shaft. By contrast, needle movement is impeded with the claimed invention by structure that is larger than both the shaft circumference and the nominal gasket opening. Luther does not meet those requirements.

Under the circumstances, there is no support for the rejections based on Luther and they should be withdrawn.

Jagger et al U.S. Patent No. 4,781,692
and Chang et al U.S. Patent No. 5,419,766

All of the claims are also rejected as allegedly obvious over Jagger in view of Chang. For reasons set out below, these rejections are also traversed.

As claimed, the blocking means or member is coupled to the tip protector in order to enclose the needle cannula tip within the tip protector (claim 1) or block the tip protector opening with the needle cannula tip proximal of the distal opening of the tip protector (claim 15). Yet, in Jagger, the stylet 100 is never pulled all the way into element 106 (which Examiner calls the tip protector). Instead, as readily seen in Fig. 5, the stylet is only pulled partially into that "protector" and has its sharp tip protruding beyond a seal 114 at the distal end of element 106 so as to extend into the flexible plastic tubular catheter 104. Examiner now agrees that it would not have been obvious to modify the tubular part of element 106 below element 114 with blocking means. Instead, Examiner asserts obviousness on the basis that the blocking means could be at the distal end of 106 and also in 104. While it is questionable whether element 106 even extends above seal 114, Examiner's obviousness position is submitted to be inappropriate.

Examiner argues that one of skill in the art knows about needle sticks and so would turn to the tab of Chang. But what Examiner overlooks is that in Jagger, the stylet is pulled into element 106 with tip still in catheter 104 for use. In that position, the tip is already enclosed. Movement of the stylet in that use position is not shown to be of concern. By contrast, in Chang, the sharp-tipped element is to be removed and disconnected completely from the catheter structure. It is in those contexts that there is a need to capture the tip within the tip protector and block the opening into the tip protector. No such problem is shown to arise in Jagger. Indeed, Jagger not only has no need for the Chang tab, it may not work with such a tab.

Unlike Chang where the catheter hub is exposed for connection to a fluid system after the needle cannula is removed and taken away, Jagger provides fluid coupling via an adaptor 118 which flows fluid through tubing and into and through the lumen of the stylet. That arrangement is necessary because the stylet stays with the catheter. If the tab of Chang is to

function to block the tip of the stylet and the opening of the tip protector (in Examiner's combination), then the tab would necessarily also get in the way of proper fluid transfer in and/or out of the tip of the stylet. Clearly, it cannot be said to be obvious to modify Jagger in order to accommodate the Chang tab when to do so would render Jagger ineffective and perhaps even non-functional for its intended purpose.

It has been settled law for nearly half a century that obviousness is negated where the proposed modification or combination of prior art changes the principle of operation of the prior art invention being modified. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Even the Supreme Court's recent *KSR* decision considers that such a combination is non-obvious. In that case, the Supreme Court of the United States made abundantly clear that obviousness requires that there be a reasonable expectation of success. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727 (2007). See also Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of Supreme Court Decision in *KSR International Co. v. Teleflex, Inc.*, 72 Fed. Reg. 57,526 (October 10, 2007). Going against the purpose and principle of a reference, as required by the rejections here, can hardly be expected to meet with success.

Hence, it is respectfully submitted that the rejections based on Jagger and Chang are in error and should be withdrawn.

Conclusion

In view of the foregoing amendments and comments, it is respectfully submitted that the application is in condition for allowance. Accordingly, a formal Notice of Allowance is respectfully solicited. In the event that any issues remain outstanding, Examiner is invited to contact the undersigned to expedite prosecution of this application. Other than the fees for the RCE and for a one month extension of time which are being paid concurrently herewith, no other

fee is believed due with this paper. If any other fee is due or is not otherwise properly paid, the Commissioner is authorized to charge any such fee or credit any overpayment to Deposit Account No. 23-3000.

Respectfully submitted,
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